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09/941,001

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Mark A. Sanner

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12/16/2004

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NEW YORK, NY 10017-5612

EXAMINER

MORRIS, PATRICIA L

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/941,001

Applicant(s)

SANNER ET AL.

Examiner

Patricia L. Morris

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 3, 17-24 and 27-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-16, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1, 2, 4-16, 25 and 26 are under consideration in this application.

Claims 3, 17-24 and 27-43 remain held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

Election/Restrictions

The requirement is still deemed sound and proper and is therefore made **FINAL**.

Again, claims 16, 25 and 26 have been examined to the extent readable on the treatment of Alzheimer's disease, exclusively.

Again, this application has been examined with regard to the **elected species** wherein R^1 , R^7 , R^{10} and R^{11} represent non-heterocyclic groups, R^4 is (C₆-C₁₄)aryl (optionally substituted by nonheterocyclic groups), R^3 is $-\text{CO}(\text{CR}^{10}\text{R}^{11})_n$, n is 0-3 and R^2 as set forth in claim 1, exclusively. It is suggested that the nonelected compounds be deleted.

This application contains claims 3, 17-24 and 27-43 drawn to an invention nonelected with traverse in the reply filed March 19, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-16, 25 and 26 are rejected under 35 U.S.C. 102(a), (b) and/or (e) as being anticipated by Pervarello et al and Seki et al. for the reasons set forth in the previous Office action.

Again, Pervarello et al. specifically disclose the instant compounds having the same use wherein R¹ is a cycloalkyl, R² is hydrogen, n is 0 or 1 and R⁴ is aryl. Note the specific reference compounds recited in columns 6-9 therein.

Again, Seki et al. teach the instant compounds wherein R¹ is t-butyl, R² is hydrogen, n is one and R⁴ is phenyl.

Hence, the instant compounds are deemed to be anticipated therefrom.

Applicant feels it is unnecessary to discuss each reference. Applicants merely assert that they have deleted n is 0. However, this amendment does not overcome the references of Pervarello et al. and Seki et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-16, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Pervarello et al., Ferruccio et al., Malle et al., Lepage et al., Daidone et al. I-III, Sato, Burow and Seki et al.

As discussed supra, the references generically embrace the instant compounds having the same use. Note, for example, the compounds in columns 6-9 of Pervarello et al., or the compounds of Seki et al.

Applicants appear to argue that one having ordinary skill in the art would not have been motivated to produce the compounds encompassed by the claims. The motivation is not abstract but is always related to the properties or uses that one having ordinary skill in the art would have expected the resulting compound to exhibit. In situations involving chemical compounds bearing a close structural similarity, the requisite motivation stems from the expectation that compounds exhibiting closely similar structures will exhibit similar properties. In the situation here, one would not have to modify the disclosure of the references, but merely employ compounds that are generically embraced by the disclosed formulas of Pervarello et al. and Seki et al. as previously discussed, the

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requisite motivation for producing the claimed compounds stems from the fact that they are generically disclosed. Therefore, one having ordinary skill in the art would have found it prima facie obvious to select any on the compounds embraced by the generic formula, including those of the claims, with the expectation that each of them can be used for the treatment of Alzheimer's disease.

Further, the references teach compounds that differ from the compounds herein as being homologs. For example, the instant compounds wherein R^1 is cyclobutyl are just the next adjacent homologs of the cyclopropyl compounds of Pervarello or the compounds wherein n is 1 are the next adjacent homologs of the compounds of Ferruccio et al., Malle et al., Lepage et al., Daidone et al. I-III and Burow, Jr. One having ordinary skill in the art would have been motivated by the disclosure of the prior art compounds to arrive at the instant compound.

In regard to n , it has long been established that this type of structural relationship-varying the size of a linking carbon chain – is per se obvious. Specifically, In re Shetty, 195 USPQ 753, In re Wilder, 195 USPQ 426 and Ex parte Gresham, 121 USPQ 422 all feature a compound with a C_2 link rejected over a compound with a C_1 link. Ex parte Ruddy, 121 USPQ 427 has a C_3 link unpatentable over a C_1 link.

The motivation to make the instant compounds is their close structural similarities to the disclosed compounds. Note that the disclosed compounds are useful for the treatment of Alzheimer's disease, thus the skilled artisan would expect such structurally similar compounds to possess similar properties.

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The exact utility here is not required in all of the references, see In re Dillon (II), 16 USPQ2d p. 1897+ when this type of close structural obviousness is obvious to one of ordinary skill in the art.

Applicants do not point to any objective evidence which demonstrates that the claimed compounds as a class exhibit any properties which are actually different from the closest prior compounds embraced by Muller et al. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977); In re Hoch, 428 F.2d 1341, 166 USPQ 406 (CCPA 1970).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

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Again, there is no enablement is shown for the treatment of Alzheimer's disease. The specification lacks any *in vitro* or *in vivo* tests. There are no working examples anywhere in the specification.

The disclosure provides no indication of whether the compounds treat any Alzheimer's disease.

Contra to applicants' arguments in the response, the state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (ie., what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

It is the state of the art that there is no known cure or prevention for Alzheimer's disease and that there are only four medications available in the United States available to temporarily slow the early stages of Alzheimer's disease. The current drugs for the treatment of Alzheimer's disease, Aricept, Exelon, Reminyl and Cognex, treat early stages of Alzheimer's disease by delaying the breakdown of acetylcholine. Memantine, which blocks excess amounts of glutamate treats last stage Alzheimer's disease. (URL: <http://www.cnn.com/2003/HEALTH/conditions/09/24/alzheimers.drug.ap/index.html>).

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The quantity of experimentation needed is undue experimentation. One of the skill in the art would need to determine which compound if any actually treats Alzheimer's disease.

Genetech, Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ 2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Again, Claim 7 lacks antecedent basis because the substituents defined for R^1 are not found in claim 1. Where is the substituent $-NR^{10}R^{11}$, R^{10} , $-C(O)NR^{10}R^{11}$, etc., found in Claim 1? Claim 1 fails to clearly claim what is intended by applicants.

Again, Claim 16 provides for the use of the treatment of Alzheimer's disease but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Again, Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

It is apparent that applicants fail to understand the rejection. Claim 16 is a composition yet applicants have drafted in terms of use. Note lines 1-3 of claim 16.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

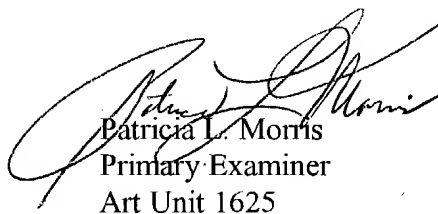
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris
Primary Examiner
Art Unit 1625

plm
December 14, 2004